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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,367	VAN MEETEREN, NORMAN	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4152005 & 12062005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Request under 37 CFR 1.105*.

DETAILED ACTION

Claim Objections

1. Claims 1, 6, 22, 23, 28 are objected to for containing a blank line where the ATCC accession number should be. Appropriate correction is required.

Further in claim 28: in line 2, the term, "into" should be replaced with –in--, as the method is for modifying the fatty acid or carbohydrate metabolism *of* SG4911NRR.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 6, 22, 23, 24, 28, and 29: the claims are indefinite for the recitation, "SG4911NRR". This is an arbitrarily assigned name for a soybean variety. It does not define any traits possessed by the variety. This name can also be changed or arbitrarily assigned to any other plant line. Inclusion of the ATCC accession number into claims 1, 6, 22, 23, and 28 will obviate the rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any hybrid soybean seed produced by crossing a soybean plant of line "SG4911NRR" with any different soybean plant; or a hybrid soybean plant, or parts thereof, produced by growing said hybrid seed.

The specification provides some morphological and physiological characteristics of plants of soybean line "SG4911NRR" (paragraphs [0054]-[0069], pages 9-10).

A review of the full content of the specification indicates that seed of soybean plant SG4911NRR, hybrid seed produced by crossing a SG4911NRR plant with any other soybean plant, are essential to the operation and function of the claimed invention.

A review of the language of claims 9 and 10 indicates that they are drawn to a genus, i.e., any and all F1 hybrid soybean seeds, and the hybrid soybean plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing soybean plant SG4911NRR with a second, distinct soybean plant. Variation is expected in the complete genomes and phenotypes of the different F1 hybrid species of the genus, since each hybrid has one non-SG4911NRR parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-SG4911NRR parent. As a result, the complete genomic

structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ. Any given specie of the claimed genus would not be representative of any other specie. Given the breadth of the claims encompassing all hybrid soybean seeds and plants produced by crossing SG4911NRR with any other soybean plant, it is submitted that the specification fails to provide an adequate written description of the multitude of soybean seeds and plants encompassed by the claims.

4. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn towards seed of soybean line SG4911NRR. Claims 2-33, are drawn towards a soybean plant produced by growing said seed, methods comprising using soybean plant SG4911NRR, hybrid soybean seeds and plants having SG4911NRR as a parent, and products produced from the methods.

The claimed seed of soybean variety SG4911NRR is essential to the claimed invention. It must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. A deposit of the seeds of inbred soybean line SG4911NRR with an

acceptable depository is required. Page 29 of the specification indicates that a deposit of said seed with the ATCC has not yet been made.

If the seeds will be deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, must also be submitted, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must by maintained. See 37 CFR 1.801-1.809.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

5. Claims 23-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods of introducing a desired trait or modifying fatty acid or carbohydrate metabolism in soybean line SG4911NRR wherein fourth or higher backcross progeny plants are selected, does not reasonably provide enablement for the claimed methods when fewer than a fourth backcross progeny plants are produced. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards methods of introducing a desired trait or modifying fatty acid or carbohydrate metabolism in soybean line SG4911NRR, comprising crossing said soybean line with a soybean line comprising one of the recited traits, or one of the recited nucleic acid molecules, selecting progeny plants comprising the trait or nucleic acid molecule, crossing them with SG4911NRR to produce backcross progeny plants, selecting backcross progeny plants having the desired trait or nucleic acid molecule and characteristics of SG4911NRR listed in Table 1, repeating the crossing step with SG4911NRR one or more times to produced selected second or higher backcross progeny plants comprising the desired trait or nucleic acid molecule and all the characteristics of SG4911NRR listed in Table 1 at the 5% significance level; and plants produced by said methods.

The specification discusses introducing single genes into soybean plants by crossing a first variety of interest with another "donor" parent plant, which contains the single gene that is to be introduced into the first variety. The progeny of that cross is then backcrossed with the first variety. The progeny of the backcross gets backcrossed with the first variety several more times, until a plant is recovered that has essentially all of the desired morphological and

physiological traits of the original, first variety in addition to the trait (single gene) transferred from the donor parent (specification, pages 24-25).

The practice of crossing two plant varieties, each expressing two different desired traits for example, to obtain a single variety that expresses both desired traits is well established. However, the specification does not teach any SG4911NRR plants produced by the claimed methods, wherein the resultant plant retains all the morphological and physiological traits of Table 1 in addition to exhibiting the introduced single trait, wherein only three or fewer backcross and selection steps are performed. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a plant that retains several of the original traits, in addition with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single locus conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the

various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Narvel et al. (Crop Sci., 2001, Vol. 41, pages 1931-1939) teach that soybean breeding programs have failed to yield cultivars comprising an introgressed locus conferring insect resistance due to factors such as inadequate resistance levels, inferior seed yield, poor agronomic characteristics, and retention of undesirable alleles from the donor plant, affecting any number of traits because of tight linkage with the insect resistance alleles (page 1931). Narvel et al. also assert that linkage drag is often regarded as a limitation to the use of nondomesticated germplasm, and that the extent of linkage drag depends on numerous variables, such as population size, the number of meiotic generations before selection is applied, and the genomic location of the locus of interest (page 1937). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of backcross conversions taught in the prior art, in order to yield the claimed plants which are to differ from SG4911NRR in only a single locus and trait, or even a single gene. It is suggested that claims 23 and 28 be amended to indicate in step (e) that steps (c) and (d) are repeated three or more times in succession, to produced selected fourth or higher backcross progeny plants.

Claim Rejections - 35 USC § 102 & 103(a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 8-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eby (U.S. Patent No. 6187998, issued February 13, 2001).

The claims are broadly drawn towards seed of soybean line SG4911NRR; a soybean plant produced by growing said seed; tissue culture of cells from tissues of said plant; a method of producing F1 hybrid soybean seeds comprising crossing SG4911NRR with a different soybean plant, and hybrid soybean seeds and plants produced by said method; methods of producing male sterile, herbicide resistant, insect resistant, or disease resistant soybean plants, or soybean plants having modified fatty acid or carbohydrate metabolism, comprising transforming soybean plant SG4911NRR with a transgene conferring one of said traits; a method of introducing a desired trait into soybean line SG4911NRR, comprising crossing SG4911NRR with another soybean line that has the desired trait, and plants produced by said method.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Byrum et al. (U.S. Patent No. 6,365,804, issued April 2, 2002).

The claims are broadly drawn towards any hybrid soybean seed, plant, or parts thereof, produced by crossing a first soybean plant with soybean designated "0491729".

Byrum et al. teach hybrid soybean seeds, and soybean plants produced by growing said seed, and parts of said plant (claims). The soybean seeds, plants, and plant parts may have been produced from a method different from those of the instantly claimed soybean seeds, plants and plant parts. However, the instantly claimed products do not appear to differ from the products taught by the reference. The instant claims do not recite any limitation(s) that would distinguish the products from those of the reference. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

6. Claims 1-29 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

June 12, 2006

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638

ATTACHMENT TO OFFICE ACTION

Request for Information under 37 CFR § 1.105

1. Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. This request is being made for the following reasons:

Applicant is claiming a seed comprising at least 50% of the genome of soybean line SG4911NRR, and soybean plants produced in methods that comprise performing crosses with soybean plant SG4911NRR. However, the instant specification is silent about what starting materials and methods were used to produce soybean line SG4911NRR. The requested information is required to make a meaningful and complete search of the prior art.

3. In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

(i) What were (are) the original parental soybean lines used to produce soybean line SG4911NRR? Please supply all of the designations/denominations used for the original parental soybean lines and line SG4911NRR. Please supply information pertaining to the lineage of the original parental lines back to any publicly available varieties.

(ii) What method and method steps were used to produce soybean line SG4911NRR?

(iii) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, had any of said parental soybean lines or progeny therefrom been disclosed or made publicly available? If so, under what

designation/denomination and under what conditions were said parental soybean lines or progeny disclosed or made publicly available and from when to when?

(iv) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, were any other soybean lines produced by said method using said original parental soybean lines, and if so, had said produced soybean lines been publicly available or sold? If so, under what designation/denomination and under what conditions were said other soybean lines disclosed or made publicly available and from when to when?

3. If Applicant views any or all of the above requested information as a Trade Secret, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.

4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure. Please indicate where the relevant information can be found.

5. The fee and certification requirements of 37 CFR § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR § 1.105 are subject to the fee and certification requirements of 37 CFR § 1.97.

6. The Applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR § 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

7. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER